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UNCLAS TAIPEI 002731

SIPDIS

STATE FOR EAP/RSP/TC, STATE PASS USTR FOR WINELAND, WINTERS  
AND FREEMAN, USDOC FOR 4431/ITA/MAC/AP/OPB/TAIWAN/MBMORGAN

E.O. 12958: N/A

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SUBJECT: TAIWAN DOH ISSUES EMERGENCY EXTENSION FOR MEDICAL  
DEVICE IMPORTS

REF: TAIPEI 2626

1. The Taiwan Department of Health issued an administrative notice on June 20 that allows the emergency importation of medical devices for an additional six months. Medical device manufacturers that have applied for registration of their products but have not yet received licenses will be allowed to continue to import their products until December 20, 2005. Those manufacturers that did not apply for registration by June 20, 2005 will not benefit from this amendment. Those products that have been registered and have received import licenses (as of June 17 barely 200 out of more than 4000 applications) can be imported without restriction. An informal AIT translation of the relevant portion of the announcement is below.

2. AIT informal translation of the relevant portion of the DOH announcement: "The implementing regulations shall be amended as follows: Article 4 -- The written application shall be reviewed in accordance with agreed procedures, the applicant having followed the relevant registration rules and having paid the registration fee within the deadline according to the relevant procedures.

"While awaiting the results of the review, the applicant must, in accordance with the inspection result regulation, pay the inspection fee within the deadline and at the same time enclose all relevant information and necessary samples in accordance with the inspection procedures.

"(amended) The competent Central Health Authority, due to the public's critical need, after the application has been filed, is able to issue a six month temporary permit."

3. Comment: The Department of Health told manufacturers and AIT on June 17 that the administrative notice would allow the continued importation of all medical devices that have submitted registration applications but not yet received licenses. An additional six months should give DOH ample time to work through its backlog of applications. However, given the slow pace of registration approvals DOH's ability to avoid another snafu is far from certain. End Comment.  
PAAL